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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/650,369 | POTTER ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**
 claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
 herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS
 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative
 of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- ☒ This communication is responsive to the Response of September 2, 2004.
- ☒ The allowed claim(s) is/are 11-18,20-27,29-36 and 38-45.
- ☐ The drawings filed on _____ are accepted by the Examiner.
- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the
 International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements
 noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF
 INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of
 Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of
 each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
- ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the
 attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

- Attachment(s)**
- | | |
|--|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>11-2-2004</u> . |
| <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of the claims

1. Currently, claims 11-18, 20-27, 29-36, 38-45 are pending in the application. In the prior action, mailed on June 30, 2004, claims 10-14, 19-23, and 28-32 were rejected; claims 15-18, 24-27, and 33-36, were objected to; and claims 37-45, and 60-62 were withdrawn as to non-elected inventions. In the Response filed on September 2, 2004, claims 11-13, 15, 16, and 38-45 were amended; and claims 10, 19, 28, 37, and 60-62 were cancelled.

2. Claims 11-18, 20-27, 29-36, and 38-45 are allowed.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Roberta L. Robins on November 2, 2004.

The application has been amended as follows:

Each of claims 11 to 13, 15, 16, and 38 to 45 has been amended by replacing the phrase "multiple epitopes fusion polypeptide" with the term - - multiple epitope fusion polypeptide- -.

Each of claims 29 to 36 has been amended to delete the term "A" at the beginning of the claim, and insert the phrase - - An isolated- - in its place.

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The amendment was made to maintain consistent language with the terms in the specification, and to clarify that the host cell claims were directed to host cells isolated from an organism.

The claims were found allowable because they do not read on naturally occurring polynucleotides, and there is no suggestion in the art for the making and use of polynucleotides encoding multiple epitope fusion proteins comprising the indicated epitopes of the Streptococcus GapC protein. It is noted that the independent claim 15 is drawn to polynucleotides encoding polypeptides comprising epitopes "from a Streptococcus GapC protein" that correspond to the specifically identified epitopic regions of GapC. I.e., the polypeptide must comprise at least one of each of the indicated regions from a Streptococcus GapC protein, and comprise GapC protein epitopes derived from at least two different species of Streptococcus.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claim 10 was objected to because of the following informalities: it is suggested that the term "epitope" in line 3 of the claim be replaced with the term - - epitopes- - to reflect that multiple epitopes are required by the claim. In view of the cancellation of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 103

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5. **(Prior Rejection- Withdrawn)** Claims 10, 13, 14, 19, 22, 23, 28, 31, and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,063,386, issued to Dale et al. (Dale), in view of WO document 93/14198, naming Fischetti et al. as inventors (Fischetti), in light of Hafid et al., Comparative Biochemistry and Physiology B, 119:493-503 (Hafid), and further in view of U.S. Patent Number 5,198,215, issued to Bernard J. C. H. De Cueninck. In view of the cancellation/amendment of the rejected claims, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 11, 12, 20, 21, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dale in view of Fischetti as applied to claims 10, 13, 14, 19, 22, 23, 28, 31, and 32 above, and further in view of U.S. Patent 6,391,316 issued to Potter et al. (Potter), or U.S. Patent Application Publication 2001/0014335, naming Saitoh et al. as inventors (Saitoh). In view of the cancellation/amendment of the rejected claims, the rejection is withdrawn.

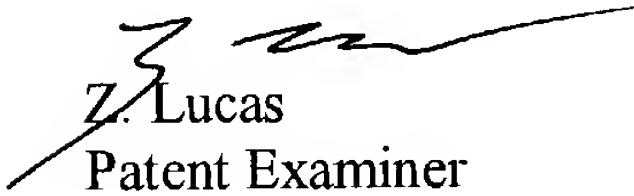
Conclusion

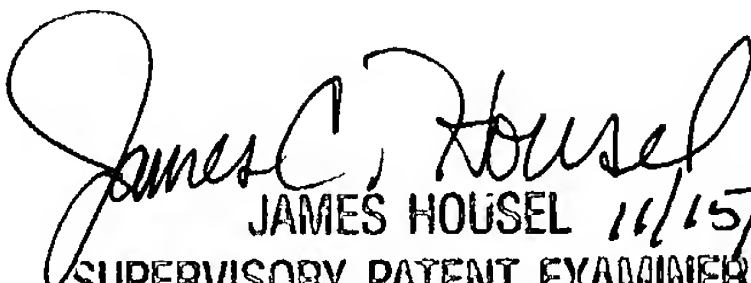
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 11/15/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600